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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,580	08/20/2001	Sandor Szalma	MOLESIM.025A	5589

20995 7590 10/31/2005

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,580	SZALMA ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13, 21, and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 19 July 2005, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 13, 21, and 22 are currently pending. Claim1-12 and 14-20 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 21 and 22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for the reasons set forth in the previous Office Action. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Applicants Arguments

1. Applicant argues that "if a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known or contemplated, 35 USC 112 is satisfied (MPEP 2164.01(c))".

This is not persuasive, as this argument pertains to utility and not to enablement. While the two are linked, the rejection is one of enablement and not utility.

2. Applicant further argues that "the specification teaches one way of how to perform element (a)". Applicant goes on to state that those of skill in the art would know how to identify which proteins in various biochemical chains would cause a pathogen to die if they were effectively removed.

The Examiner agrees with Applicant. However, it is pointed out that the claims are not limited to proteins that would cause a pathogen to die if they were removed.

3. Applicant argues that the specification teaches how to perform element (b), (c), and (d).

Applicant is reminded that the enablement rejection pertains to step (f) in the claims, in which a potential target for pharmaceutical intervention is identified. The pertinent part of the previous Office Action is reiterated below:

The specification provides no direction on how detecting differences between the pathogen protein fingerprint and a human protein fingerprint elucidates information about a potential target for pharmaceutical intervention. The specification states that the "protein/ligand interaction comparisons comprise identifying the nature of the ligand interaction with each protein in the comparison. Typically the protein/ligand interaction is characterized by a bonding affinity between each protein and each ligand. This could be binary or it could be a numerical variable, such as an equilibrium binding constant or a binding energy (page 7, beginning line20)". Without guidance on the specific generation of the binding constant or the binding energy or perhaps some other variable that would represent a fingerprint, the present invention is not enabled. The specification at page 7 describes an interaction between four ligands and five proteins, which are not named. The nature of the interaction is characterized by bonding affinities and protein annotations are made based upon the interaction assessment and a pattern is established unique to a certain protein. It is unclear from these steps how one would get to step (f) from steps (a)-(e) in the instant claims. How does the protein fingerprint tell anything

pertinent to a target for pharmaceutical intervention? There are no parameters that indicate what the binding affinity values mean in terms of pharmaceutical intervention. For instance, is binding a positive indicator or a negative indicator? Are degrees of binding assessed? What is the correlation between the fingerprint and a disease, for instance? How does detecting differences in fingerprints tell one anything about a potential target? Just because binding affinities are different does not indicate that the random proteins from the human genome and the proteins from the pathogen are in any way similar or could be potential targets. At what point would one of skill in the art know if the pathogen target is analogous to the human target? There are several thousand proteins in the human genome. Are all of these analyzed?

4. Applicant states that the specification notes that fingerprint comparisons indicate whether two proteins are structurally or functionally associated. Applicant further states that higher overlap values indicate proteins with similar chemical response while lower overlap values indicate divergent chemical response.

It is noted that these limitations are not recited in the instant claims and therefore, the argument is not persuasive.

5. Applicant argues that "the specification teaches to determine the interaction fingerprint overlap".

This is not persuasive because while the specification teaches to determine the overlap it does not teach how to determine it such that a potential target pharmaceutical intervention is identified. It is also noted that these limitations are not present in the instant claims.

6. Finally, Applicant argues that the pathogen may be identified as the best candidate for pharmaceutical intervention based on low average or low maximum overlap with human proteins because such low overlap indicates that a drug binging to the potential target protein will not

likely bind to human proteins. Accordingly, the specification teaches one way to perform the identifying step.

This is not persuasive, as those limitations are not present in the instant claims. Further, those steps are not consonant with the claimed limitations in step (f). Applicant is reminded that the specification must have a reasonable correlation to the entire scope of the claim [MPEP 2164.01(b)].

Conclusion

The outstanding rejection under 35 USC 112, 2nd paragraph has been withdrawn in view of the claim amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Marjorie A. Moran
10/20/05

MARJORIE A. MORAN
PRIMARY EXAMINER

October 19, 2005
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow